Information System. *Id.* at (g)(1)(b)(i).

40. By way of example, under the Florida Medicaid Program the determination of whether a drug is eligible for reimbursement and prescribed for a purpose that is covered by Medicaid is governed by 42 U.S.C. 1396r-8, Chapter 465 F.S., and the Florida Medicaid Prescribed Drug Services Provider Handbook.

41. In addition to the statutory authority granted by 42 U.S.C. 1396r-8 allowing state Medicaid programs to exclude or otherwise restrict coverage of outpatient prescription drugs, pursuant to the Florida Medicaid Prescribed Drug Services Coverage, Limitations, and Reimbursement Handbook to be reimbursed by Medicaid, a drug must be medically necessary and prescribed for medically accepted indications and dosages found in the (A) drug labeling ("labeling" means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers, or accompanying such article), the (B) American Hospital Formulary Service Drug Information, the (C) United States Pharmacopeia-Drug Information or the (D) DRUGDEX Information System.

42. Lilly knew or should have known the Medicaid regulations governing prescription drug reimbursement.

42. Whether the use of a drug is medically necessary was material to Medicaid's decision to reimburse for prescription. Consequently, the government would have denied reimbursement for claims made for prescriptions of Zyprexa if it had known the purpose for which the drug had been prescribed was medically unnecessary.

43. Use of Zyprexa, for example, for dementia, or for anxiety or depression in the elderly is not supported by the compendia as medically safe and effective, and therefore should not have been covered by the State of California's Medicaid programs, yet nonetheless, Lilly recklessly has promoted Zyprexa for those and other unauthorized, untested and unproven uses through the methods alleged in this Complaint.

44. Lilly expected and intended its unlawful Zyprexa promotional efforts to cause claims for reimbursement to be submitted to, *inter alia*, Medi-Cal. Lilly designed and implemented its aggressive off-label Zyprexa promotional tactics with the intent to

influence the prescribing choices of long-term care and primary care physicians who treat Medi-Cal beneficiaries. The intended and foreseeable effect Lilly's avaricious scheme was that the Medi-Cal would fund the cost of treatment with Zyprexa through its reimbursement claims system and accordingly, in turn, Lilly would directly and substantially increase its Zyprexa revenue stream at *inter alia* Medicaid expense.

45. Until recently, the State of California was unaware of the unlawful manner in which Lilly promoted Zyprexa off-label within the state and nationally.

46. Under the California False Claims Act, it is unlawful for any "person," as defined by the statute, to submit a false or fraudulent claim to Medicare and Medicaid. The act of submitting a false claim includes by causing another to submit a false claim as well as soliciting, receiving, offering or paying any kickback, bribe or rebate in connection with a Medicaid claim. Cal. Govt. Code §12651.

47. The California False Claims Act provides for penalties of up to $10,000.00 for each violation of the foregoing provisions.

48. Lilly has caused false claims to be submitted to Medicaid for reimbursement through its promotional efforts in violation of the California False Claims Act.

49. In summary, throughout the country and in the State of California, Lilly aggressively and intentionally marketed Zyprexa for non-indicated uses and non-medically necessary uses including for the treatment of general mood and behavior disorders, attention deficit disorder, the attention deficit hyperactivity disorder, depression ***not*** associated with psychosis, sleeplessness, autism, Alzheimer's, dementia and aggression and agitation associated with dementia and Alzheimer's. Further, Lilly has intentionally misrepresented to prescribers who treat Medicaid participants that Zyprexa is safer than less expensive, generic antipsychotics such as Haldol which costs pennies per day rather than the extraordinary expense of Zyprexa.

50. By and through this and other conduct, Lilly caused tens of thousands of prescription reimbursement claims for Zyprexa prescribed for medically unnecessary and non-indicated uses to be submitted to the Medicaid/Medicare programs for reimbursement.

However, the prescription drug reimbursement claims for off-label uses of Zyprexa Lilly caused to be submitted to the Government as a direct result of its unlawfully off-label promotion campaign were not eligible for reimbursement from Medicaid, the VA or CHAMPUS/Tricare (and Medicare Part D, when it came into effect on January 2006) because such off-label uses were neither listed in the labeling approved by the FDA nor otherwise supported as safe and effective by any of the drug compendia specified by the Medicaid statute.

51. Lilly engaged in its national Zyprexa promotional blitz with the knowledge that the majority of Zyprexa prescriptions written as a result thereof are reimbursed by government-funded health programs such as Medicaid, as well as with the knowledge that such prescriptions were for non-medically accepted indications and non-medically necessary uses of Zyprexa that fall outside the coverage of Medicaid.

VII. BACKGROUND

A. FDA Regulation of Drug Companies and their Marketing Practices

52. As detailed below, Lilly's conduct also materially and wantonly violated the FDA's regulations and federal law governing off-label marketing and truthful labeling and promotion of prescription drugs. Lilly engaged in this profit-driven misconduct for the purpose of deceiving physicians with their false and fraudulent off-label marketing message to cause the submission of false claims for Zyprexa to the State of California.

1) The FDA's Regulation of Promotional Activities of Drug Manufacturers

53. A prescription drug's product labeling contains the drug's indication. Drug product labeling broadly defined by federal regulation, including 21 C.F.R. § 202.1(k)(2), which provides that drug manufacturers' marketing and promotional materials for their drugs aimed at physicians, *i.e.*, all brochures, handouts, detail aids, slide shows or other such promotional materials, are also defined as "product labeling" and are stringently regulated as such. By law, representations made in any labeling material must be truthful, not misleading and represent a fair balance of the information presented. Any failure to

fairly and accurately represent the required information about a prescription drug is considered misbranding and is a false and fraudulent statement as a matter of law. *See* 21 U.S.C. §§ 331(a) and (b), 352(a), (f) and (n); 21 C.F.R. § 201.57.

54. Pharmaceutical promotional materials and presentations lacking in fair balance or that are otherwise false or misleading, violate the Food Drug and Cosmetics Act, 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated hereunder. Such violations exist where promotional and marketing materials and presentations for an FDA approved drugs reference "off-label" uses or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated or are otherwise false, misleading or lacking in fair balance in the presentation of information about the drug being marketed or any competing drug.

55. "Off-label" prescribing of drugs occurs when a drug is used by a medical professional beyond the drug's indication. This includes prescribing a drug for a condition not indicated on the label, treating the indicated condition at a different dose or frequency than specified in the label, or to treat a different patient population (*e.g.* treating a child with the drug when the drug is approved to treat adults).

56. Lilly materially violated these clear-cut labeling and misbranding regulations to illegally increase sales of its blockbuster drug in the off-label elderly market by and through its marketing and promotional efforts of its LTC sales force in direct-to-physician marketing.

57. Lilly, unable to control and bolster Zyprexa revenues by directly submitting prescription drug reimbursement claims to Medicaid and Medicare, instead launched a campaign intended to increase Government-funded off-label purchases of Zyprexa by defrauding LTC physicians, pediatric physicians and primary care physicians ("PCPs") to prescribe Zyprexa. The natural, intended and foreseeable consequence of such unlawful, premeditated conduct caused physicians and pharmacists to submit claims to publicly-funded health plans that were ineligible for reimbursement pursuant to these programs' regulations.

58. Each such claim Lilly knowingly caused to be submitted under these false pretenses in derogation of the labeling and misbranding laws, and each false statement it made to get claims for Zyprexa paid, constitutes a false claim for which Lilly is accountable under the California False Claims Act.

2) Federal Law Prohibits Off-Label Marketing To Protect the Health and Safety of Patients

59. Off-label marketing by pharmaceutical companies is closely regulated by the FDA and the law because of its inherent dangers. These regulations protect patients and consumers by insuring that drug companies do not promote drugs for uses other than those found to be safe and effective by an ostensibly independent, scientific governmental body, the FDA.

60. Under the Food and Drug laws, (1) a manufacturer may not introduce a drug into interstate commerce with an intent that it be used for an off-label purpose (notably, however, Lilly's creation of a LTC sales division directly evidences Lilly introduced Zyprexa into interstate commerce with the specific intent that it be used for off-label purposes, *i.e.*, to treat vague cross-over symptoms in the elderly, as pleaded with specificity herein), and (2) a manufacturer illegally "misbrands" a drug if the drug's labeling describes intended uses for the drug that have not been approved by the FDA. 21 U.S.C. §§ 331, 352.

61. Physicians are not prohibited from prescribing an FDA-approved drug "off-label"; however, pharmaceutical promotional activities and marketing materials and presentations are false or misleading in violation the Food Drug and Cosmetics Act and regulations promulgated hereunder if they advertise "off-label" uses of a drug, or expressly or implicitly promote unapproved uses and dosing regimens for which the drug is not indicated.

62. When pharmaceutical companies illegally encourage off-label uses for their drugs, the number of prescriptions rises, thereby causing Medicaid and other programs to pay out more for prescriptions that are not eligible for payment. Lilly intended for its "off-label" promotional campaign to improperly increase the submissions of off-label Zyprexa

prescriptions, including such prescriptions reimbursed by the Medicare and Medicaid programs.

63. Lilly's off-label marketing programs have been extremely successful, leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

64. Any claim submitted for a drug when the drug was prescribed for an off-label use not only violates Medicare payment rules but also files a fraudulent claim under the False Claims Act. 31 U.S.C. §3802. Claims for Zyprexa prescriptions induced to be written and submitted by Medicaid/Medicare participating pharmacy benefits providers to the Government for reimbursement as a direct and foreseeable result of Lilly's illegal off-label marketing campaign has caused the State of California to suffer substantial economic harm.

B. Zyprexa's Limited Indicated Uses

65. In September of 1996, the FDA approved Zyprexa tablets for use in the treatment of adults of schizophrenia at target doses of 10 mg. per day. In 2001, the Zyprexa tablets were approved for treatment of adults suffering from acute manic episodes associated with bipolar I disorder at dosages of up to 20 mg. per day. In July of 2003, Zyprexa tablets were approved for the short-term treatment of adults suffering from acute manic episodes associated with bipolar I disorder, in combination with lithium or **Depakote (valproic acid)**, with a recommended doses of 10 to 20 mg. per day. In January of 2004, Zyprexa tablets were approved for long-term treatment of adults diagnosed with bipolar disorder in doses of up to 20 mg. per day.

66. In 2001, Lilly launched ZYPREXA Zydis, an orally disintegrating tablet form of Zyprexa. ZYPREXA Zydis was specifically identified as an "opportunity" in Lilly's 2001 LTC Business Plan.

67. ZYPREXA Zydis tablets were made available in 4 strengths: 5 mg, 10 mg, 15 mg, and 20 mg. ZYPREXA Zydis has essentially the same efficacy and safety profile as

regular ZYPREXA tablets, and is indicated by the FDA for the same conditions: schizophrenia, maintenance of treatment response in schizophrenia and acute mania associated with bipolar I disorder in patients experiencing a manic or mixed episode.

68. The purpose of the introduction of the new disintegrating tablet form of Zyprexa was for "Convenient Administration." Because this Zyprexa tablet is formulated to easily dissolve within seconds of being placed in the patient's mouth, the drug was touted by Lilly as an important additional option for treating elderly patients, who may have difficulty swallowing a regular tablet form. In addition, Lilly promoted Zydis as providing a convenient alternative to liquid formulations of other drugs, and because absorption is not affected by food, it can be taken without regard to meals or drinking liquids, although, if patients wanted to drink something along with the medication, they may, but it is not necessary.

69. Lilly provided Plaintiff-Relator with training materials to assist in the promotion of ZYPREXA Zydis in the LTC demographic.

1) Medical Compendia Limited Supported Uses of Zyprexa

70. The HFS, the United States Pharmacopeia–Drug Information and the DRUGDEX information system support the use of Zyprexa in adult (not geriatric) schizophrenic or bipolar patients **only**. The uses supported by the three compendia and the FDA approved labeling are collectively defined as Zyprexa's "Medically Accepted Indications" in the Federal Medicaid Act, 42 U.S.C.A. § 1396r-8. Neither the compendia cited above nor the FDA-approved labeling supports any use of Zyprexa by the elderly, by children or for treatment of adults with depression, anxiety, ADD, ADHD, sleep disorders, anger management, mood enhancement or mood stabilization.

VIII. PLAINTIFF-RELATOR'S PERSONAL KNOWLEDGE OF LILLY'S SUCCESSFUL, NATIONAL OFF-LABEL ZYPREXA MARKETING AND PROMOTIONAL PRACTICES

71. In or about February 2001, Lilly hired Plaintiff-Relator as a Long Term Care ("LTC"), Specialty, Pharmaceutical Representative.

72. Plaintiff-Relator's hiring came on the heels of one of Lilly's expansions of its LTC sales division. Since Lilly established the LTC sales division, which upon information and belief occurred simultaneously with the drug's launch in 1996, Lilly periodically expanded the LTC sales division.

73. At the time Lilly hired Plaintiff-Relator, there were 160 LTC Zyprexa sales representatives whose territories spanned the United States. See Exhibit "A." Initially, there were only 15 LTC sales representatives. In August 1999 that number was expanded to 59. In March 2000, concomitant with Zyprexa gaining sales momentum in the LTC market, Lilly nearly tripled its LTC sales force to 160. *Id.* Lilly continued to increase the size of its LTC sales force thereafter.

74. Lilly's stated purpose for expanding the LTC division was to, *inter alia*, maximize Zyprexa sales to patients who receive their medications *via* a LTC pharmacy. Indeed, Lilly even disseminated materials to LTC sales representatives overtly referring to the "Golden Opportunity in LTC Care" and the data that supported the vast potential for Zyprexa sales in this off-label market.

75. Lilly maintained a Zyprexa LTC sales division to fulfill one purpose - to aggressively promote Zyprexa on behalf of Lilly to LTC facilities that care exclusively for the elderly, despite the lack of any clinical trials or FDA approval for the use of Zyprexa in the elderly. Plaintiff-Relator gained personal knowledge of these facts during Lilly employment and has evidence substantiating these facts in the Lilly documents she retained from her Lilly employment, some of which are attached hereto as Exhibits. As alleged herein and in the expanded discussion of Lilly and its off-label promotion of Zyprexa in section IX, Lilly trained its LTC sales force to maximize Zyprexa's LTC care revenues.

76. For the duration of her employment with Lilly, Plaintiff-Relator's territory encompassed the LTC market for parts of Northern California, which she covered alone, and the scope of her employment was to promote, market and generate increased revenues from sales of Zyprexa prescriptions written to elderly LTC nursing home residents. Plaintiff-Relator detailed the Stockton Territory within the Sacramento District which

encompassed Modesto, Stockton, Lodi, Mantica, Oakdale, Ripon and the surrounding regions.

77. Plaintiff-Relator was required by Lilly to participate in and to graduate from a rigorous 4 week training course at Lilly's corporate headquarters in Indianapolis, Indiana.

78. There were 17 "new hire" LTC sales representative trainees from all over the United States in Plaintiff-Relator's training class. The LTC sales division was uniform throughout the country. All LTC sales representatives received uniform training, they all received the same Zyprexa marketing materials (of course all geared to selling Zyprexa to elderly patients) and all LTC sales representatives market Zyprexa in the LTC demographic in essentially the same manner, no matter which state and which territory.

79. The first two weeks of training focused on Zyprexa. The training topics included an "introduction" to the drug and what it does, the fundamentals about Zyprexa's competitor drugs and training about why Zyprexa is comparatively superior. LTC trainees were also given studies about Zyprexa, Zyprexa's competitors, Zyprexa's effectiveness compared to placebo and/or other atypicals and other similar studies that trainees were required to memorize. The purpose of memorizing these studies was for the Lilly LTC trainees to cite to and explain in detail these Zyprexa-supporting studies during sales calls on LTC physicians. Plaintiff-Relator was given Lilly training materials in connection with her training and was continuously tested throughout her training to monitor her progress.

80. The second two weeks of the training period focused entirely on how to sell Zyprexa to elderly patients in LTC skilled nursing facilities. In reality, this aspect of Lilly's training was a study in how to successfully market Zyprexa and induce physicians to prescribe Zyprexa to elderly patients to treat symptoms such as agitation, irritability, dementia and the like, all of which constitutes illegal off-label marketing.

81. Among other things, Plaintiff-Relator received extensive training from Lilly corporate training officials on subjects such as how to talk about the drug's efficacy in the treatment of Alzheimer's patients, how to induce physicians to ask "unsolicited" questions about Zyprexa off-label uses and to focus the marketing message on symptoms and

behaviors and Zyprexa's superior efficacy in "Restoring Calm," and that "nothing calms like Zyprexa." The sales materials discussed below carry forward this "Calming" selling message.

82. Lilly reinforced this training by providing mandatory role playing sessions designed to replicate what the LTC sales person would experience in the field when calling on LTC physicians.

83. Among other things, Lilly LTC salespersons including Plaintiff-Relator, engaged in role playing exercises that emulated physician sales calls. Lilly made it a prerequisite to "graduation" from Lilly's initial rigorous 4 month training for each LTC sales representative to receive a passing grade on a *videotaped* role-playing session designed to simulate "real life" marketing calls with LTC physicians.

84. Since Zyprexa has not been approved by the FDA to treat the elderly, Lilly trained its LTC sales persons (through such exercises as role playing) to discuss Zyprexa's efficacy and safety in treating generic symptoms known by Lilly to be commonplace in elderly LTC patients. The primary symptoms LTC sales representatives were trained to focus on were hostility and aggression, and to highlight Zyprexa as the drug of choice to "restore calm" in such agitated patients.

85. Notably, Plaintiff-Relator received scant training on schizophrenia and bi-polar disorders during the four weeks if her comprehensive LTC sales training. Instead, the majority of the training involved geriatric data and information. Lilly's focus on geriatrics over Zyprexa's indicated uses evidences Lilly's illegitimate purpose in maintaining a LTC sales division and reveals its focus and intent to achieve blockbuster off-label sales of Zyprexa. The calculated sales and marketing tactics demonstrate Lilly's conscious aforethought to off-label marketing.

86. Plaintiff-Relator, having worked in the pharmaceutical sales prior to Lilly, vocally questioned her Lilly trainers about the legality of the marketing practices being taught, specifically, she questioned the off-label nature of the Zyprexa marketing campaign promoting Zyprexa's safety and superior efficacy for geriatrics to LTC physicians, nursing

home employees and LTC pharmacies. Plaintiff-Relator was assured that by following Lilly's training on how to deliver the LTC Zyprexa message, off-label regulations would not be violated.

87. The role-playing seminars were not limited to LTC training. Rather, mandatory role-playing occurred at every Lilly sales meeting so sales representatives could "brush up" and hone their skills in delivering the misleading, deceptive and illegal Zyprexa off-label marketing tactics.

88. In addition to communicating such practices during frequent regional and district sales conferences, Lilly engrained its off-label marketing message during once or twice annual national sales meetings. During national sales meetings, specific gatherings, seminars, and training sessions were held solely for the Lilly LTC sales representatives.

89. As is detailed below, once Plaintiff-Relator graduated from training, she was continuously given Zyprexa marketing materials, such as studies, LTC implementation guides and "detail aids" tailored to selling Zyprexa in the geriatric market. Lilly's Zyprexa sales materials were the creation of the Zyprexa Brand Team, the division within Lilly responsible for developing the marketing and promotional selling message for Zyprexa in the United States.

90. Plaintiff-Relator also occasionally received promotional materials distributed by her Lilly manager, Dan Tubridy ("Tubridy"). One egregious example of such materials was a one-page sheet containing 2 form letters (one for Zyprexa and one for Zyprexa Zydis) with "fill in the blanks" to personalize the message to client-target physician and his or her geriatric patients Zyprexa doses and times of administration. See Exhibit "B." The letter's purpose was to suggest to the physician that his or her patients' Zyprexa dosage should be increased to reduce "nursing time and effort." Tubridy instructed Plaintiff-Relator to pass out this form letter to her target-physicians to induce an increase in Zyprexa dosage, which translated directly to increased Zyprexa sales revenues, by promoting Zyprexa's known side effect of somnolence. Promotion of Zyprexa as a chemical restraint for difficult, agitated elderly patients was not only illegal unsolicited off-label marketing, but also a wanton

derogation of patients' fundamental human rights.

91. Lilly's myopic focus and goal of driving Zyprexa off-label sales is evidenced by the convoluted manner in which LTC sales representatives' performance was evaluated. Job performance hinged entirely upon each LTC representatives *total sales revenues* generated by LTC Zyprexa purchases in her Northern California territory. Lilly's tunnel vision focus on salespersons profits, rather than number of prescriptions written evidences the avaricious nature of Lilly's illegal marketing pursuit, as it shows salespersons were expected not only to increase market share, but to increase dosages and/or frequency to rive up profits.

92. Plaintiff-Relator was continuously employed as a Lilly LTC sales representative for three years until on or about June 2003. At that time, she voluntarily resigned from her employment to accept a higher-paying pharmaceutical sales representative position with another pharmaceutical company. Plaintiff-Relator began pursing a career change while still a Lilly employee after Lilly executives rebuffed her attempts to rectify the unethical and illegal Zyprexa sales practices implemented and mandated by her Lilly Supervisor, Dan Tubridy.

93. Indeed, prior to leaving Lilly's employ, Plaintiff-Relator submitted to Lilly corporate a 3 page summary documenting all of Tubridy's illegal and unethical conduct. Exhibit "C." Lilly's rebuffed Plaintiff-Relator's attempt to right the wrongs of her manager, simply giving Tubridy a meaningless "warning," which was tantamount to a corporate endorsement of Tubridy's illegal, but successful Zyprexa sales methods. Soon thereafter, Plaintiff-Relator began seeking employment with another pharmaceutical company.

IX. ADDITIONAL FACTUAL BASIS OF LILLY'S ILLEGAL OFF-LABEL MARKETING OF ZYPREXA FOR ELDERLY OFF-LABEL USES AND TO PRIMARY CARE PHYSICIANS FOR OFF-LABEL USE TO TREAT NON-SCHIZOPHRENIC OR BIPOLAR ADULTS

94. As alleged supra in § VII B, Zyprexa is indicated to treat an exceptionally small subset of the United States population. Indeed, less than 7% of the United States'

adult population has been diagnosed with one of the rare mental illness for which Zyprexa is indicated for the treatment of symptoms relating thereto – schizophrenia and bipolar disorder.

95. It is not by stroke of luck that Zyprexa has been Lilly's largest selling drug for a number of years and has generated astounding blockbuster revenues for the drug company. For years, Zyprexa generated several billions of dollars of revenue for the company and was among the top ten best selling drugs in the world. In 2003, Zyprexa sales rose to $4.4 billion and assumed the rank of world's fifth best selling drug.

96. Rather, from the outset, Lilly recognized the promotion of Zyprexa's not medically accepted indications and not medically necessary uses as the key to Zyprexa's blockbuster success, i.e., promoting the use of Zyprexa to treat off-label demographics who present with symptoms akin to those exhibited by patients diagnosed with those exceedingly rare mental illnesses – depression, sleeplessness, agitation: 1) elderly LTC residents, 2) depressed and distracted adults who are not diagnosed with schizophrenia or bipolar disorder and 3) children with conditions such as ADHD, autism, mood disorders and disruptive children. Lilly devised this game plan despite its awareness of numerous serious treatment emergent side effects caused by Zyprexa including diabetes, hyperglycemia, extraordinary weight gain and metabolic syndrome, to name a few.

97. Indeed, Lilly funded calculated studies with methodologies intended to contrive positive clinical data about Zyprexa to ensure Zyprexa's numerous, dangerous and even deadly side effects were kept from public purview.

98. Lilly succeeded. Zyprexa's incredible revenues and sales ranking directly stems from the drug's dangerous overuse off-label that have not been found by the FDA or medical compendia to be safe or effective. This dangerous overuse is directly attributable to Lilly's illegal off-label promotional tactics.

99. Upon information and belief, based upon the foregoing, Lilly began planning its national, aggressive off-label marketing campaign for Zyprexa even before Zyprexa had received FDA approval. In this regard, Lilly's devised a strategy prior to Zyprexa's launch

to market the drug not only for use with elderly and children, but also for a constellation of broad symptoms in the broad realm of mood and thought disorders, a strategy that gave rise to an ongoing pattern of false and misleading conduct.

100. This conduct directly and proximately resulted in both the submissions of claims for not medically accepted indications and not medically necessary uses of Zyprexa to Medicaid, Medicare, VA and CHAMPUS/Tricare programs in California and throughout the country as well as adverse health effects among participants of those programs.

101. Through this planning Lilly funded clinical studies for Zyprexa, for on and off-label uses, which ultimately Lilly planned to be used by its sales representatives to promote Zyprexa. Indeed, Plaintiff-Relator was given such studies by Lilly with the expectation that she learn the details of the studies backwards and forwards and use the contrived results of the studies in promoting Zyprexa off-label.

102. Lilly furthered its illegal avaricious Zyprexa business plan by creating a deceptive and misleading marketing campaign to create a LTC market for Zyprexa, among other off-label markets. Lilly falsely touted Zyprexa's superior efficacy in treating the generic mood and behavioral symptoms of schizophrenia and bipolar disorder; symptoms that Lilly knew were also prolific in the elderly population.

103. The purpose of the deceptive scheme was to create the misimpression that geriatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category were Zyprexa candidates, thereby creating a broad, ill-defined market for Zyprexa in the elderly demographic.

104. Lilly tweaked the message slightly for its other sales divisions, such as its primary care physician sales force, to achieve the same impact - to create the misimpression that adult and pediatric patients presenting with a myriad of symptoms that did not fit into a precise diagnostic category would benefit from being prescribed Zyprexa in increasing doses, thereby creating an across the board off-label for Zyprexa among patients who relied upon Medicaid, Medicare, the VA and/or CHAMPUS/Tricare to fund their necessary prescription drug needs.

A. Lilly's Calculated Training Of Zyprexa Sales Representatives to Successfully Market Zyprexa Off-Label to, *inter alia*, Medicaid/Medicare Beneficiaries

105. Lilly's scheme was highly successful. Data shows that well over half of all dollars spent on Zyprexa is spent on non-medically accepted or not medically necessary uses. Moreover, Zyprexa has been prescribed to more than 12 million people worldwide since the atypical antipsychotic's launch in 1996. Crucial to this Blockbuster success was Lilly's aggressive marketing of Zyprexa for elderly use through its LTC sales division, which consisted chiefly of exaggerating the drug's uses, while concealing its life-threatening side effects.

106. Lilly created complicated marketing structures that appeared independent from their proprietary of promotion forces.

107. Lilly sales representatives were expected in the course and scope of their employment to identify specific doctors (*i.e.* physicians who were already prescribing large volumes of Zyprexa or physicians whose antipsychotic "business" Lilly wanted to obtain) to recruit and communicate Lilly's interest in funding research opportunities and clinical trials at their institutions. Doctors who were willing to speak favorably about Zyprexa often were given substantial funds by Lilly in the form of research grants, many unrestricted. These funds were in reality kickback paid to induce the physicians' use of Zyprexa.

108. Lilly engaged in this duplicitous conduct to create the false perception that respected physicians were using and investigating Zyprexa's efficacy in non-medically accepted and not medically necessary uses on their own initiative, and not as a result of Lilly's marketing activities. And in addition to providing free travel to resorts, free lodging and free meals, Lilly also paid these physicians to give talk segment medical education seminars, advisory boards, consultants meetings, speakers bureaus and similar events that favorably discussed not medically accepted and not medically necessary uses of Zyprexa.

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1) Promotion to the Elderly

109. The generic symptoms Lilly unlawfully promoted Zyprexa to treat mimicked those of dementia and/or Alzheimer's, including agitation, anxiety, and insomnia. By marketing the drug for the treatment of ***symptoms*** for which Zyprexa was not approved, Lilly violated strict FDA labeling regulations detailed *infra*.

110. Lilly encouraged use of Zyprexa in the elderly demographic to treat multiple symptoms that might be categorized as relating to dementia and/or Alzheimer's. To assist in these efforts, Lilly created patient profile detail aids whose focus was on "behavior treatment" such as agitation, suspiciousness, depressive mood, anxiety, and lack of concentration. By focusing on symptoms rather than the diagnoses of schizophrenia or bi-polar disorder, Lilly intended to overcome Zyprexa's lack of any FDA approved market for Zyprexa in the LTC demographic.

111. Lilly propagated the intentionally misleading message that Zyprexa was indicated for the treatment of dementia by directing its sales force to focus on behavioral and cognitive symptoms such as anxiety, depression, agitation during physician sales calls.

112. Among the most common, treatment-emergent adverse ***side effects*** of Zyprexa and the other atypical antipsychotics is ***somnolence***. Somnolence is defined as sleepiness, the state of feeling drowsy, ready to fall asleep. Within its drug class, Zyprexa is the most heavily sedating.

113. One approach Lilly devised for its LTC sales representatives was to market Zyprexa's somnolence side effects as method to reduce patient care hours by essentially chemically restraining demanding elderly patients.

114. Indeed, Lilly preyed upon the fact that providing care to elderly LTC residents who typically exhibit combative behavior and aggression is considerably stressful, frustrating and time consuming.

115. By way of example, Plaintiff-Relator and other Lilly LTC sales representatives were given studies by Lilly to distribute to LTC staff espousing ostensibly clinical evidence that elderly patients prescribed Zyprexa required fewer skilled nursing

staff hours than patients prescribed other competing medications. One such study was Olanzapine Treatment of Psychotic and Behavioral Symptoms in Patients With Alzheimer Disease in Nursing Care Facilities, *Archives of General Psychiatry*, Vol. 57, pg. 968 (Oct. 2000) See Exhibit "N." Plaintiff-Relator and other Lilly LTC sales representatives were told to point directly to pg. 971 of this study and read:

> "A statistically significant reduction in caregiver distress, measured by the sum of the Occupational Disruptiveness scores for Agitation/Aggression, Hallucinations, and Delusions (Core Disruptiveness) was seen for patients treated with 5 mg/d of olanzapine... Caregivers of patients treated with 5 mg/d of olanzapine also had similar reductions in Occupational Disruptiveness associated with Anxiety, Appetite and Eating Disorders, Delusions, Depression/Dysphoria, and Hallucinations items."

116. Lilly LTC sales representatives were taught to create "action" in nursing homes by marketing Zyprexa's "calming" effect. In truth, this was Lilly's thinly-veiled marketing of Zyprexa as an effective **chemical restraint** for demanding, vulnerable, and needy patients.

117. In addition, Plaintiff-Relator's manager disseminated a form letter to the representatives under his supervision and control that touted Zyprexa as providing superior efficacy and safety when compared to placebo and significantly reduced caregiver burden at a dose of 5 mgs daily. See Exhibit "B." This statement was "supported" by a footnote citing a study that ostensibly supported this mendacious marketing of Zyprexa as a chemical restraint. *Id.*

118. The form letter also expressed the medical opinion that the 5 mg. dose of Zyprexa should be administered at 5 pm. *Id.* This was a Lilly-trained "5 at 5" slogan which translated essentially referred to give your patients 5 mg. of Zyprexa at 5 pm and they will sleep through the night eliminating the disruptive late night conduct demanding of caregiver time.

119. Atypical antipsychotics are powerful medications, laden with serious treatment-emergent side effects. Zyprexa is a dangerous drug even when prescribed for on-label use. It is even more dangerous for the elderly. Zyprexa and the other atypical

antipsychotics have not received FDA-approval to treat the elderly because of atypicals' serious risk of harm and the lack of scientific evidence of its safety and efficacy in this population.

120. On April 11, 2005, the FDA issued a public health advisory to alert health care providers, patients, and patient caregivers of its determination based upon clinical studies that using Zyprexa or the other atypicals to treat behavioral disorders in elderly patients with dementia is associated with increased mortality. The FDA's examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia).

121. Accordingly, the FDA required Lilly to amend Zyprexa's label to include a "black box warning" of this deadly side effect. A 'black box' designation is an FDA-recommended/mandated warning based upon clinical research studies, for certain drugs that may cause serious and potentially life-threatening side effects. The FDA requires that a black box warning be placed on the labeling or literature of a prescription drug, or in literature describing it. It is the strongest warning the FDA requires.

122. Because of Lilly's promotion of Zyprexa's somnolence side effect as an attribute of the drug, patients were intentionally medicated with incapacitating antipsychotic agents such as Zyprexa to control patient behavior, "restore calm" and reduce the time needed to be spent to treat patients, especially the those patients who required burdensome, time intensive care, as well as those patients who demonstrated "oppositional" and "defiant" behavior.

123. The use of atypical and typical antipsychotic drugs to control the behavior of elderly nursing home residents who are not psychotic constitutes an **unlawful chemical restraint**. Lilly's unlawful and unethical promotion of the use Zyprexa, off-label, as a **chemical restraint** resulted in patients being restrained in a zombie-like state, unable to complain or object. Prescriptions were medically unnecessary

124. The State of California's healthcare programs would not have paid prescription drug reimbursement claims caused to be submitted by Lilly's mendacious and

unlawful marketing of Zyprexa's somnolence side effect had it known the truth.

125. As part of the Zyprexa sales campaign, Lilly disseminated Zyprexa LTC Implementation Guides to its LTC sales representatives. Lilly created a LTC Implementation guide specifically to roll out each new year's version of Lilly's LTC patient profile. See eg Exhibit "E."

126. Lilly's LTC detail aid was a LTC stereotypical patient - an elderly patient representing the agitated, hostile geriatric patients LTC physicians treat everyday. "Rose" was the detail piece used by LTC sales representatives to represent the angry and hostile elderly patient complaining of symptoms such as anxiousness, irritability, mood swings, and disturbed sleep. See e.g. Exhibit "D."

127. The "Rose Jackson" ("Rose") detail aid contained only conspicuously printed wording like "Agitation," "Depressive Symptoms," "Aggression," Irritability," and "Sleeplessness" calculated to imply that Zyprexa was indicated for the treatment of such **symptoms**. *Id.* The top of the front page conveyed the message "Helping you bring dignity to patients' lives." *Id.* Nowhere on this Rose detail aid did Lilly explicitly disclose that Zyprexa's FDA-approval was limited to the treatment symptoms of schizophrenia and bipolar mania and not the other generic symptoms highlighted in print on the detail aid (i.e. sleeplessness, irritability, depressive symptoms). *Id.*

128. The detail piece featured a large color picture of "Rose," an elderly woman composed to appear agitated and combative. *Id.* Lilly's strategy goal for the Rose detail piece was to "encourage doctors to try Zyprexa in patients similar to the one we profile, Rose Jackson. In this way, doctors can see for themselves that Zyprexa **stabilizes symptoms and behaviors safely.**"

129. "Rose" was designed to personalize the sales representative's promotion of Zyprexa as the wonder drug to "calm" difficult patients and to reduce patient treatment time. Plaintiff-Relator was instructed to show this image to clients to reinforce the marketing message that Zyprexa can treat his or her angry, agitated and difficult patients.

130. Lilly even disseminated along with the Rose detail aid the marketing

message the sales representative was expected to learn verbatim and then deliver during LTC physician sales calls, which Plaintiff-Relator still recalls to this day. Lilly trained its sales representatives to show the Rose detail aid to physicians and deliver a verbatim sales pitch probe recommending that the physician's patients like Rose are indicated for treatment with Zyprexa and would benefit from commencing a Zyprexa regimen. By way of example, Plaintiff-Relator and other sales representatives would ask leading questions to physicians relayed in the LTC Implementation Guide, such as, "Doctor, does it make sense to use Zyprexa as a first choice for a patient like Rose, since Zyprexa helps to safely stabilize symptoms and behaviors such as agitation, anxiety, hostility, delusions, and resistance to care?" See Exhibit "E."

131. Future iterations of the Zyprexa LTC Implementation Guides similarly helped deliver the message that Zyprexa should be prescribed to treat moods, behaviors and symptoms. By way of example, in the January 2003 "Rose" Detail Aid, Lilly describes to sales representatives, including Plaintiff-Relator, that on the detail aid's cover, "there is also the addition of a couple more mood symptoms, which is to emphasize our unique ability in treating mood." See Exhibit "F."

132. When detailing the Zyprexa 2003 LTC Rose detail piece, sales representatives, including Plaintiff-Relator, were instructed to deliver the message that, "Because Zyprexa treats both symptoms of elevated mood and psychosis, it helps you restore calm to the resident, the staff and even the other residents- the environment will be less disruptive since the resident will be calm instead of yelling, 'Help me-help me.'"

133. Further, on the cover of later versions of the Zyprexa LTC Rose detail piece, along with the symptoms and behaviors, Lilly finally incorporated the language, "ZYPREXA is indicated for the treatment of" and then lists the two approved indications for use for Zyprexa, schizophrenia and acute bipolar mania. Exhibit "G."

134. Among the other duplicitous sales tactics implemented by Lilly at the corporate level involved serious violations of the confidentiality of protected health information safeguarded by the HIPAA regulations as well as breaches of the doctor-patient

privilege.

135. Although Lilly LTC salespersons were evaluated on total Zyprexa sales revenues rendering prescribing physicians, the LTC pharmacies, Lilly LTC sales representatives' relationships with LTC pharmacies were nonetheless pivotal in successfully promoting Zyprexa within the LTC context.

136. Indeed, LTC pharmacies arrange for and bill the State of California' for the drugs prescribed by physicians to LTC facility residents. LTC pharmacies are known as 'closed-door' pharmacies. Closed-door pharmacies are full-service pharmacies, but which exclusively provide prescription drug delivery services to residents of LTC facilities.

137. LTC pharmacies regularly bill Government-funded healthcare plans such as Medicaid for medications prescribed by medical professionals working onsite at the nursing homes.

138. When a patient in a nursing home requires a prescription medication, physicians give written or verbal prescription orders for their patients to nurses. The nurses transmit the prescription orders verbally or by facsimile to the responsible LTC pharmacy clerical data entry personnel to be entered into the LTC pharmacy's computerized order entry system.

139. Once a physician's prescription order is processed in the LTC pharmacy's order entry system, a pharmacist fills the prescription based on the physician's request and the medication is then shipped to LTC skilled nursing home facility where the patient resides.

140. Once the LTC has filled and shipped a prescription, the LTC pharmacy prepares a claim for submission to the Government, including the State of California, seeking reimbursement for the cost of the prescription drug.

141. Lilly knew that the vast majority of elderly LTC residents rely upon, *inter alia*, Medicare and Medicaid to fund in whole or in part their prescription drug costs.

142. Since LTC pharmacies play an integral role in the delivery of prescription drugs to LTC residents, LTC pharmacies were also "clients" of LTC sales representatives

which were targeted for Zyprexa off-label marketing, albeit less frequently than the physicians who are writing the prescriptions.

143. To identify and target the most influential doctors, Lilly encouraged LTC representatives to develop personal relationships with the LTC pharmacies to gain access to the pharmacies' local prescribing data.

144. In addition, LTC pharmacies provide consultant pharmacist services to the LTC facilities they service. Such consultant pharmacists work closely with physicians writing orders in LTC facilities to purported "educate" LTC physicians about prescription alternatives.

145. Because of the significant influence LTC pharmacies play in the prescribing decisions of LTC physicians, Plaintiff-Relator made once monthly sales calls to LTC pharmacies in her territory to ensure the pharmacies encouraged the use of Zyprexa in the facilities they service. Plaintiff-Relator specifically recalls making sales calls to LTC pharmacies to combat financially-incentivizing rebate agreements the LTC pharmacies had negotiated with Janssen, the manufacturer of Zyprexa's competitor Risperdal. Such rebate agreements made it *profitable* for the LTC pharmacy to use its consulting pharmacists power and influence to push LTC physicians to use Risperdal over Zyprexa.

146. Plaintiff-Relator and the LTC sales division generally were also instructed and trained on how to obtain Drug Utilization reports, also known by the acronym "DURs," from the LTC skilled nursing home executive staff. See Exhibit "G."

147. A "Drug Utilization Report" is a report delineating protected health information detailing which patients were taking which drugs and which physician was prescribing those drugs.

148. Lilly enforced this directive by tracking LTC sales representatives' success rates in obtaining the coveted DUR reports. See e.g. Exhibit "H."

149. To keep the LTC sales representatives across the nation abreast of Zyprexa LTC sales as well as successful LTC promotional tactics, Lilly disseminated a LTC Best Practices Newsletter 4 times a year. *Id.*

150. The LTC Best Practices Newsletter is packed with evidence and admissions of Lilly's unlawful LTC off-label marketing campaign. *Id.* It openly addresses Lilly's improper expectation that Lilly LTC sales representatives gain access to protected confidential patient information (i.e. DURs), instructs the sales representative to do rounds with the "NH [nursing home] prescriber" – a highly offensive invasion upon the doctor patient privilege, and contains messages from Lilly executives such as Grady Grant and Tom Olinski, Lilly National Sales Directors and Mike Murray – the LTC Western Division Sales Director and identifies LTC top sales performers across the nation to "SELL ZYPREXA!" The Newsletter also features a "Coaches Corner," which provides tips on maximizing LTC sales of Zyprexa. In the 2003 Winter edition of the Newsletter, the Coaches Corner featured an article by "Wayne Mielke, [the] "Long Term Care Coaching Champ of 2001, on the importance of **DUR ATTAINMENT**." *Id.*

151. Plaintiff-Relator received the quarterly Lilly LTC Best Practices Newsletter in the course and scope of her Lilly employment.

152. Lilly paid honoraria or speaker fees as part of their overall off label Zyprexa marketing scheme. The payment of and acceptance of the financial incentives in exchange for prescriptions violated the federal Anti-Kickback Statute. See § XI.

153. Lilly management approved huge speaker fee budgets as a means to disguise large payments to physicians who were willing to prescribe Zyprexa off label. Lilly established large budgets for each LTC representative to induce physicians to write off label. The speaking fees were typically $1500 for a "lunch and learn."

154. One method employed by Lilly to conceal kickback payments under the guise of legitimacy was the creation of a "speaker" program. Lilly even established an annual budget for LTC sales representatives to "invest" in speaker fees/honoraria as well as an annual entertainment budget to impress and attract physicians' business.

155. Physicians were even "groomed" by Lilly to be speakers by attending all-expense paid speaking seminars in resort-like atmospheres. These seminars were in truth designed to market Zyprexa, not to provide speaker training. For large volume prescribers,

regardless of whether they exhibited a shred of public speaking acumen, after the seminar such physicians were retained and paid handsomely to speak about Zyprexa.

156. The speaking engagements were frequently a mere sham, indeed, Plaintiff-Relator has personal knowledge that such Lilly-paid speakers were even paid to give pointless presentations to their colleagues at the healthcare facility with which they were affiliated.

157. Such thinly-veiled kickback payments were made with the intent that in return, the paid physician would prescribe Zyprexa for symptoms and illnesses that were unrelated to schizophrenia and bipolar disorder to the frail elderly population. Lilly LTC sales representatives used their improper access to DURs to identify physicians to solicit to enter into unlawful financial relationships.

158. Plaintiff-Relator has personal knowledge that Lilly established similar illegal referral relationships with health care providers throughout the United States.

159. Sales representatives, including Plaintiff-Relator, were instructed by Lilly on implementing "Peer-to-Peer Programs" intended on having paid physicians lecture on designated topics, including off-label topics. Typically, sales representatives, including Plaintiff-Relator, would organize continuing medical education ("CME") programs and offer these programs to their physician customers.

160. By way of example, one such program was "FDA Regulated Programs (Promotional)" wherein the sales representative selects a program topic and a physician under contract with Lilly Lecture Bureau. If the chosen speaker is not under contract, he or she must sign a contract to speak about Lilly's products. See Exhibit "I." The Sales representative submits a speaker payment request to Lilly's Lecture Bureau.

161. To complete the payment process to physicians, Plaintiff-Relator would contact the Lilly Lecture Bureau and the Lilly Lecture Bureau arranged for the check to be sent, typically directly to the lecturing physician. See Exhibit "J."

162. Lilly's Peer to Peer Programs Implementation Guides stresses that the "program time should be balances equally with entertainment time." See Exhibit "K."

Further, the sales representative was instructed to pre-set menus and "pre-select wine list and order group appetizers." *Id.*

163. Another example of a Lilly Peer to Peer Program is the Independent Scientific Exchange (Non promotional Program). This program is ostensibly initiated by the medical institution. The institution contacts the sales representative or Lilly Lecture Bureau directly. Then, Lilly's Lecture Bureau sends the specific institution their "grant request letter." See Exhibit "L." The grant request may contain a request for an honorarium to speak, as well as a request for food, beverages, travel and other expenses. LLB sends grant checks to the institution or physician within 7 days after completion of the program, and sometimes prior to the program. *Id.*

164. Further, by way of example, sales representatives could also initiate "Customer Entertainment" as a Peer to Peer Program. The sales representative invites customer physicians to specific events (i.e., sporting events, concerts, theater or dinners). If the incentive of choice was a dinner, the sales representatives were instructed to select the best items on the menu and select a red and white wine for the table." See Exhibit "M."

165. Lilly's routine practice of paying kickbacks was intended to and did amplify physicians' off-label overutilization of Zyprexa for their patients.

166. Lilly knew that the payments constituted kickbacks in reckless disregard of the law. Lilly was also acutely aware that the safe harbors established by the HHS did not cover the exorbitant payments being made. Lilly intended these payments to encourage Zyprexa overutilization in off-label demographics.

2) Illegal Off-Label Marketing to Primary Care Physicians

167. Lilly's national off-label Zyprexa marketing campaign targeting primary care physicians ("PCPs") was designed to make Zyprexa part of the everyday prescribing habits of not only LTC physicians treating the elderly, but also PCPs in their office practices.

168. In order to grow Zyprexa market share sales and surpass competing antipsychotics such as Risperdal, Lilly undertook a scheme to market and promote Zyprexa

for off-label purposes beyond LTC, Lilly concomitantly launched a marketing campaign targeting PCPs. The campaign was designed to "educate" PCPs about which patients they regularly see in their practices who present with symptoms treatable with Zyprexa, *i.e.*, albeit off-label use. Lilly's goal being to make Zyprexa the cornerstone of PCPs everyday prescribing habits.

169. Similar to the LTC sales message, Lilly's PCP off-label Zyprexa promotional campaign focused on symptoms, not diagnoses. To achieve this goal, Lilly PCP sales representatives were trained to deliver a Zyprexa marketing message that centered on symptoms associated with mood, thought, and behavioral disturbances.

170. Lilly targeted PCPs because of the fundamental role PCPs play in patient care and in prescribing drugs to treat a multitude of symptoms, thereby maximize profits and growing market share. In addition, Lilly marketed Zyprexa to primary care physicians for non-indicated uses, because Lilly's marketing studies demonstrated that PCPs generally had less awareness of Lilly's indicated uses and treatment-emergent side effects. Lilly sales material encouraged representatives to promote Zyprexa as a "safe, gentle psychotropic" suitable for people with mood-related symptoms.

171. Lilly PCP sales representatives were trained and instructed to market Zyprexa to PCPs by suggesting that there were a plethora of patients in the physician's practice exhibiting "irritability," "disruptive behavior," "poor sleep," "elevated mood," "depressed mood," "anxiety" and "irregular sleep patterns" and that Zyprexa is a safe and efficacious drug to treat such symptoms.

172. Just as it did for the LTC sales force, Lilly created several promotional caricatures tailored to market Zyprexa to PCPs. The primary PCP caricature Plaintiff-Relator became familiar with is "Donna." "Donna" is a mother of two children in her early 30's who is distracted and depressed and these symptoms are interfering with her daily life. Perhaps Donna has been prescribed drugs that treat depression. Lilly sales representatives were trained and instructed to encourage PCPs with "Donnas" in their practice to prescribe Zyprexa, although she has not been diagnosed with either bipolar mania or schizophrenia.

173. Lilly developed Donna knowing that millions of people fit Donna's broadly defined profile and who are not psychotic, schizophrenic, or bipolar. This way, Lilly could accomplish its primary goal to drive off-label sales of Zyprexa by causing as many unsuspecting adult patients on Zyprexa as possible.

174. Plaintiff-Relator has personal knowledge that Lilly's promotion of Zyprexa to PCPs, including her presence in PCP physicians' offices during a Lilly PCP sales representative's sales call.

175. Each LTC sales representative's territory "overlapped" with a Zyprexa PCP sales representative. Lilly expected its LTC representatives to coordinate with his or her overlap.

176. Accordingly, Plaintiff-Relator periodically made joint sales calls to PCPs who also treated LTC residents with her "overlap." During these joint Zyprexa sales calls, Plaintiff-Relator witnessed her Lilly PCP overlap deliver the Zyprexa off-label PCP marketing message designed to promote Zyprexa's superior efficacy and safety for treating adult patients who presented with symptoms relating to mood, anxiety, and depression, while omitting that Zyprexa is not indicated for the treatment of such symptoms not attendant to the diagnosis of bipolar disorder or schizophrenia.

177. Plaintiff-Relator witnessed the PCP overlap use, wherein the PCP sales representatives referred and relied upon the Donna profile to promote Zyprexa off-label for depression and mood disorders. At no time did the PCP sales representative initiate any discussion about Zyprexa's lack of indication for the treatment of such symptoms in patients not diagnosed with schizophrenia or bi-polar disorder.

178. Lilly's efforts to promote Zyprexa for use as a general mood stabilizer in the treatment of depression have resulted in billions of dollars of revenue for the company.

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X. LILLY CAUSED THE SUBMISSION OF FALSE CLAIMS FOR ZYPREXA REIMBURSEMENT TO BE SUBMITTED BY LONG TERM CARE PHARMACIES

A. Zyprexa Prescribed Off-label to LTC Residents Was Ineligible for Reimbursement by the Medicaid Program

179. Prior to the enactment of the Medicare Part D program, Medicaid purchased an estimated 80-90% of atypical antipsychotic prescriptions. Of the top 30 drugs by total US revenue, Zyprexa is the most expensive. As detailed herein, the FDA defines off-label use as indications, dosage, form, dose regimen, population or other use parameter not mentioned in the approved labeling.

180. Because prescriptions for off-label uses generally are not eligible for reimbursement, under Medicaid and Medicare regulations, submission of a claim for reimbursement for a drug prescribed off-label constitutes a false claim for the purposes of the State of California's False Claims Act. While it is a pharmacy, by virtue of the reimbursement system, which unwittingly submits the false prescription drug claim, the person or persons who knowingly cause(s) such a claim to be presented to the State of California, including the State of California, is liable under the law. Here, Lilly's California False Claims Act violations arise from its successful attempts to induce LTC pharmacies to unwittingly defraud the State of California.

181. Lilly knew that medically unnecessary, off-label Zyprexa prescriptions were ineligible for Medicaid reimbursement and that its activities would, in fact, cause numerous ineligible prescriptions to be submitted to Medicaid and Medicare by the LTC pharmacies which arranged for pharmaceutical benefits to LTC patients.

182. The unwitting participation of the LTC pharmacies in the submission of false claims was not only foreseeable; it was an intended consequence of Lilly's scheme of fraud.

183. Absent Lilly's intentional, illegal off-label marketing in the LTC demographic, and its unlawful financial relationships with doctors, Zyprexa would not have been prescribed off-label. Lilly's off-label marketing programs have been extremely

successful, leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

184. Each Zyprexa claim submitted to the State of California for Zyprexa prescribed for an off-label use not only violates Medicare payment rules, but constitutes the submission of a fraudulent claim redressable by California's False Claims Act, Cal. Gov. Code §§ 12650 et seq.

185. The remedial provisions of the California's False Claims Act is the necessary vehicle to obtain redress for the substantial economic harm suffered by Medi-Cal as a result of the millions of dollars of Zyprexa reimbursement claims caused to be written and submitted by enrolled Medi-Cal pharmacy benefits providers to the State of California as a direct and foreseeable result of Lilly's illegal off-label marketing campaign.

186. Lilly's wanton misconduct has been ongoing since at least 2001.

XI. THE CALIFORNIA FALSE CLAIMS ACT

187. The California False Claims Act, Cal. Gov. Code §§12650 et seq., provides, in pertinent part that a person is liable to the State of California for a civil penalty of up to $10,000, plus not less than two times and not more than three times the amount of damages which the State of California sustains because that person, *inter alia*,:

(a) Liability for certain acts. Any person who—

(1) Knowingly presents, or causes to be presented, to an officer of the state or of any political subdivision thereof, a false claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or by any political subdivision;

(3) Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(4) Has possession, custody, or control of public property or money used or to be used by the state or by any political subdivision and knowingly delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state or by any political subdivision and knowingly makes or delivers a receipt that falsely represents the property used or to be used;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property;

(7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision; or

(8) Is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

188. Under § 12650(b) (1) – (3) of California's False Claims Act, "Knowing" and "knowingly" mean that a person, with respect to information, does any of the following: (1) Has actual knowledge of the information, (2) Acts in deliberate ignorance of the truth or falsity of the information or (3) Acts in reckless disregard of the truth or falsity of the information. Proof of specific intent to defraud is not required.

XII. DEFENDANT LILLY'S VIOLATIONS OF THE FEDERAL AND CALIFORNIA ANTI-KICKBACK STATUTES CAUSED FALSE CLAIMS TO BE SUBMITTED TO THE GOVERNMENT

A. Federal Anti-Kickback Statute Prohibitions

192. The Medicare and Medicaid Fraud and Abuse Statute (Statute) was first

enacted under the Social Security Act in 1977. The Statute imposes criminal penalties on whomever violates the Anti-Kickback Provision and states in relevant part, whoever knowingly and willfully offers or pays remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person:

> (A) to refer an individual to a person for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase or lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal Health care program.

42 U.S.C. § 1320a-7b(b)(2)(A) & (B).

193. By its terms, the Federal Medicare and Medicaid Anti-Kickback Statute prohibits certain conduct involving improper payments in connection with the delivery of goods or services, including prescription drugs, covered by Medicare, Medicaid and other federal health care programs.

194. Illegal payments or solicitations of payments include those in cash or in kind, *i.e.*, goods, those made directly or indirectly, and those made overtly or covertly.

195. A violation of the AKS arises if *one purpose* of the payment was to induce future referrals even if the payment was also intended to compensate for professional services. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).

196. Such illegal inducement relationships between drug companies and physicians endanger patients and harm the State of California because, as is alleged herein, they encourage unnecessary treatments, contaminate the free exercise of medical judgment by physicians, limit patient options and lead to higher federal and state payments for prescription drug benefits. The Anti-Kickback Statute was promulgated to thwart such dangerous practice of medicine.

197. The remuneration paid by Lilly and accepted by participating Med-Cal

physicians all across the country, as alleged in detail *supra*, fit squarely within the AKS's definition of illegal remuneration.

198. As alleged herein, in violation of the AKS, Lilly paid, and physicians accepted, unlawful remuneration, including cash payments thinly-veiled as "speaker fees," honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa to LTC patients, children and adults, notwithstanding Lilly's knowledge of the prohibitions of offering, paying or receiving items of value in exchange for arranging the purchase of any good paid for in whole or in part by the federal government.

199. Lilly entered into unlawful inducement relationships in violation of the Anti-Kickback Statute with LTC physicians, PCPs, pediatric physicians and other medical professionals nationwide.

200. Although "safe harbor" regulations exist to protect certain relatively innocuous and even beneficial commercial arrangements, no such provision protects the kickbacks paid by Lilly.

201. Lilly prevented the State of California from knowing of the underlying violations of the federal and California AKS violations by concealing its illegal agreements with Medi-Cal participating providers as well as concealing the exchange of illegal remuneration pursuant thereto.

B. Violations of California's Health & Safety Comprehensive Compliance Program

202. California's Health and Safety Code §§ 119400-119402 relates to prescription drug and medical device marketing practices. The California Marketing Compliance Law ("CMCL") requires pharmaceutical companies and medical device manufacturers to adopt Comprehensive Compliance Programs (CCPs) that meet the standards set forth in the compliance guidance for pharmaceutical companies published by the Department of Health and Human Services' Office of Inspector General (OIG). CA Health & Safety Code §119400(a). These compliance programs must also contain provisions concerning their interactions with medical and health professionals, and adopt limits on gifts to such

professionals. Finally, the CMCL requires covered companies to make certain compliance declarations publicly. California Health and Safety Code §§ 119400-119402.

203. The CMCL applies to entities "engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and clinical synthesis." California Health and Safety Code § 119400(c). The law also states that "pharmaceutical company" also means "an entity engaged in the packaging, repackaging, labeling, re-labeling, or distribution of dangerous drugs," as well as "a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in ... [California] on behalf of a pharmaceutical company." California Health and Safety Code § 119400(c).

204. The CMCL also regulates interactions by drug and device companies with "medical or health professionals," which are defined as persons licensed by state law to prescribe drugs for human patients, a medical student, or a drug formulary committee member. California Health and Safety Code § 119400(b).

205. Drug and device manufacturers must adopt a Comprehensive Compliance Program that is "in accordance with" the Office of Inspector General's 2003 Compliance Program Guidance for Pharmaceutical Manufacturers. California Health and Safety Code § 119402(a).

206. The CMCL requires manufacturers to implement "a specific annual dollar limit on gifts, promotional materials, or items or activities" that the manufacturer may provide to medical or health care professionals, in accordance with the OIG Compliance Guidance and the Pharmaceutical Research and Manufacturers of America in July 2002 (the PhRMA Code). California Health and Safety Code § 119402(c)-(d).

207. The CMCL requires that manufacturers "annually declare" in writing that they are in compliance with their own CCP and with the CMCL. California Health and Safety Code § 119402(e).

208. By its terms, the California's Health and Safety Code §§ 119400-119402

prohibits certain conduct involving improper payments in connection with the delivery of goods or services, including prescription drugs, covered by Medicare, Medicaid and other federal health care programs.

194. Illegal payments or solicitations of payments include those in cash or in kind, *i.e.*, goods, those made directly or indirectly, and those made overtly or covertly.

195. Such illegal inducement relationships between drug companies and physicians endanger patients and harm the State of California because, as here, they encourage unnecessary treatments, contaminate the free exercise of medical judgment by providers, limit patient options and lead to higher federal and state payments for prescription drug benefits. California's Health and Safety Code §§ 119400-119402 was promulgated to thwart such dangerous practice of medicine.

197. The remuneration paid by Lilly and accepted by physicians all across the country, including the State of California, as alleged in detail *supra*, are precisely the type of conduct California's Health and Safety Code §§ 119400-119402 aims to prohibit.

198. As alleged herein, in violation of California's Health and Safety Code §§ 119400-119402, Lilly paid, and physicians accepted, unlawful remuneration, including cash payments thinly-veiled as "speaker fees," honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa to LTC patients, children and adults, notwithstanding Lilly's knowledge of the prohibitions of offering, paying or receiving items of value in exchange for arranging the purchase of any good paid for in whole or in part by the federal government and the State of California.

199. Lilly entered into unlawful inducement relationships in violation of California's Health and Safety Code §§ 119400-119402 with LTC physicians, PCPs, pediatric physicians and other medical professionals nationwide.

200. Although "safe harbor" regulations exist to protect certain relatively innocuous and even beneficial commercial arrangements, no such provision protects the kickbacks paid by Lilly.

201. Lilly prevented the State of California from knowing of California's Health

and Safety Code §§ 119400-119402 violations by concealing such agreements.

C. Defendant Lilly's Anti-Kickback Statute Violations and Violations of California's Health and Safety Code §§ 119400-119402 are Predicate Acts Giving Rise to Liability Under the State and Federal False Claim Acts

202. The Anti-Kickback Statute and California's Health and Safety Code §§ 119400-119402 work hand in glove with the False Claims Act. As a matter of law, violations of the AKS and California's Health and Safety Code §§ 119400-119402 state a cause of action under the False Claims Act. Indeed, compliance with the AKS, as well as all other relevant laws and regulations, is a condition of payment by Medicaid for prescription drug claims. 42 U.S.C. §1320a-7b(b).

203. Thus, where conduct that violates the Anti-Kickback Act or California's Health and Safety Code §§ 119400-119402 results in goods and services (here, Zyprexa) provided to Medi-Cal beneficiaries, that good or service is *ineligible* for reimbursement under Medi-Cal payment rules and federal law.

204. Thus, as a matter of law, prescription drugs and other products purchased in violation of the AKS or California's Health and Safety Code §§ 119400-119402 are ineligible for Medi-Cal reimbursement. By and through the covert payment of illegal kickbacks, Lilly defrauded, *inter alia*, Medi-Cal -participating pharmacies into presenting reimbursement claims for Zyprexa to the State of California containing the false certification that the claim was submitted in compliance with the AKS or California's Health and Safety Code §§ 119400-119402 and other applicable regulations.

205. The State of California would appropriately have denied Zyprexa reimbursement claims if it had knowledge that the Zyprexa prescription written which gave rise to the claim for reimbursement was the product of an illegal kickback arrangement.

206. Defendant Lilly, acting in concert with physicians, caused, *inter alia*, Medicaid-participating pharmacies all across the country to submit claims that were rendered ineligible for reimbursement by Lilly's violations of the AKS and California's Health and Safety Code §§ 119400-119402 as well as caused such pharmacies to explicitly falsely certify

that they were acting in compliance with all applicable laws and regulations, including the AKS, for each and every claim the pharmacies submitted. The pharmacies' certifications Lilly caused to be submitted to the State of California, however, were false when made.

207. Such pharmacies reasonably and justifiably relied upon the validity and medical appropriateness of the Zyprexa prescriptions.

208. Lilly's illegal scheme had one intended purpose and result – increasing Zyprexa profits – and therefore certified claims for Zyprexa prescriptions instead of cheaper alternatives were submitted to the State of California for payment by pharmacies throughout the nation. Accordingly, at all times relevant to the Complaint, Lilly acted with the requisite scienter.

209. The result of the Lilly's scheme was a dramatic increase in the number of claims submitted to the State of California for the higher priced Zyprexa, which led to dramatically higher revenue for Lilly. Lilly's increased revenues, and the correspondingly-increased cost to the Government healthcare programs, were the direct, intended, and foreseeable result of the unlawful kickbacks payments made by Lilly to LTC physicians, PCPs and pediatric physicians.

210. Lilly's liability under §§ 3729(a)(1) and (a)(2) of the Federal False Claims Act, §§ 68.082(a) and California False Claims Act, Cal. Govt. Code §12650 *et seq.* arises from the drug company's overt and willful participation in causing the basis for false claims to be made through the establishment of an illegal and corrupt financial relationships.

211. Lilly's conduct is also punishable under §12651 (a)(3) of the Federal False Claims Act, and California False Claims Act, Cal. Govt. Code §12650 *et seq.*, for entering into an unlawful conspiracies with the intent to defraud the Government.

FIRST CAUSE OF ACTION
California False Claims Act
Ca. Government Code §12650 *et seq.*

212. Plaintiffs reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

213. This Count is brought by Plaintiff-Relator Vicente in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a).

214. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Zyprexa, in the State of California.

215. A significant percentage of patients who use or have been prescribed Zyprexa off-label for non-medically necessary uses as a result of Lilly's unlawful off-label marketing campaign are persons whose prescriptions are paid for in whole or in part by Medi-Cal or other State funded healthcare programs.

216. At all times relevant and material to this Complaint, Lilly has induced a misallocation of California's funds through a pattern of fraudulent conduct, as alleged herein. Lilly intentionally concealed its campaign to market Zyprexa in California and throughout the United States for un-approved indications and medically unnecessary uses for the purpose of, and with the effect of, unlawfully increasing purchases of Zyprexa prescriptions by Medi-Cal that would not have funded but for Lilly's active concealment of its unlawful Zyprexa off-label marketing campaign.

217. By the conduct alleged in this Complaint, Lilly has knowingly and foreseeably caused the submission false claims for payment or approval that Lilly knew to be ineligible for reimbursement and the cost of which would be borne by California by and through, *inter alia,* Medi-Cal, to be presented to officers and employees of the State of California. Defendant has also caused false records and statements to be submitted to officers and employees of the State of California to get its false claims paid.

218. Lilly's conduct includes its deceptive and illegal scheme to expand off-label use of Zyprexa by, *inter alia*, 1) marketing Zyprexa in a misleading and/or disingenuous way for off-label uses and populations to physicians in the long term care and primary care markets and 2) orchestrating a kickback scheme pursuant to which, in sum, it paid physicians in cash and in kind in exchange for writing off-label prescriptions of Zyprexa. As a result, the California has paid false claims submitted for the Zyprexa drugs by Medi-

Cal participating pharmacies, resulting in great financial loss to the State.

219. Lilly's conduct constitutes the intentional violation of the California False Claims Act and other laws.

220. The claims for Zyprexa caused to be submitted by Lilly constitute false claims because, *inter alia*, Medi-Cal reimbursement is not available for non-medically accepted indications or non-medically necessary uses of prescription drugs as alleged herein.

221. By virtue of the above-described acts, Lilly has also knowingly and intentionally conspired to, and caused false claims for payment to be submitted for Zyprexa from the implementation of its kickback scheme as well as caused false records and statements to be submitted to get false Zyprexa claims paid. Lilly's kickback scheme violated the Federal Anti-Kickback Statute and the analogous law of the State of California and has thereby caused the submission of false claims and records to Medi-Cal.

222. It was the intended and foreseeable effect of Lilly's kickback scheme to cause pharmacies to routinely submit thousands false claims requesting reimbursement for expensive Zyprexa prescriptions.

223. The amounts of the false or fraudulent claims and records or statements caused by Lilly to be submitted to Medi-Cal were material.

224. Plaintiff California, being unaware of the falsity of the claims and statements or records caused to be made by Defendant Lilly as alleged herein, and in reliance on the accuracy thereof, paid and may continue to pay for off-label prescriptions of Zyprexa.

225. All unlawful conduct described above may have continued after Plaintiff-Relator's voluntary decision to seek alternative employment.

226. By reason of the conduct described above, California has been damaged in an amount that is believed to be in excess of tens of millions of dollars annually for claims submitted for Zyprexa in Northern California alone.

227. California is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty of up to $10,000 for each ineligible claim

submitted to Medi-Cal for payment.

SECOND CAUSE OF ACTION

Conspiracy to Submit False Claims in Violation of the California False Claims Act Ca. Gov't Code §12651(a)(3)

228. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

229. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of California causing the submission of false claims for Zyprexa. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

230. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Medi-Cal, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, California regularly made payments to pharmacies for Zyprexa.

231. The amounts of the false or fraudulent claims to the State of California were material.

232. Plaintiff State of California, being unaware of the falsity of the claims and/or statements made by Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator voluntary left Lilly's employ.

233. The State of California is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty of up to $10,000 for each ineligible claim submitted to Medi-Cal for payment.

THIRD CAUSE OF ACTION

(Violation of Business & Profession Code § 17200)

234. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

235. Plaintiffs are informed and believe and allege that Lilly, by the acts and misconduct alleged herein, violated Business and Professions Code sections 17200.

236. California Business & Professions Code Section 17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

237. The acts and practices described herein were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of Business & Professions Code Section 17200. The acts and untrue and misleading advertising set forth in presiding paragraphs are incorporated by reference and are, by definition, violations of Business & Professions Code Section 17200. This conduct includes, but is not limited to:

a. Representing to the State of California and the general public that Zyprexa was safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the State of California and the general public that Zyprexa has a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians and others that the use of Zyprexa was safe for human use, had fewer side effects and adverse reactions than other methods for treating schizophrenia and bi-polar disorder, constituted a convenient, safe form for treating schizophrenia and bi-polar disorder, even though the Defendant Lilly knew these to be false, and even though the Defendant Lilly had no reasonable grounds to believe them to be true;

c. Purposely downplaying and understating the health hazards and risks associated with Zyprexa; and

d. Issuing promotional literature deceiving potential users of Zyprexa by relaying positive information and manipulating statistics to

suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of Zyprexa.

238. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California Business & Professions Code Section 17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California Business & Professions Code Section 17500, as set forth herein.

239. The unlawful, unfair and fraudulent business practices of Defendant Lilly described above present a continuing threat to members of the public in that Defendant Lilly continues to engage in the conduct described therein.

240. As a result of their conduct described above, Defendant Lilly has been unjustly enriched. Specifically, Defendant Lilly has been unjustly enriched by receipt of billions of dollars in ill-gotten gains from the sale and prescription of Zyprexa in California, and other states, sold in large part as a result of the acts and omissions described herein.

241. Because of the fraudulent misrepresentations made by Defendant Lilly as detailed above, and the inherently unfair practice of committing a fraud against the State of California and the general public by intentionally misrepresenting and concealing material information, the acts of Defendant Lilly described herein constitute unfair or fraudulent business practices.

242. Plaintiffs, the State of California and Plaintiff-Relator, pursuant to California Business & Professions Code Section 17203, seek an order of this court compelling the Defendant Lilly to provide restitution, and to disgorge the monies collected and profits realized by Defendant Lilly, as a result of their unfair business practices.

243. Defendant Lilly's acts were willful, wanton, reckless and fraudulent; hence, the State of California and Plaintiff-Relator are entitled to exemplary damages, inter alia.

WHEREFORE, Plaintiffs demand judgment against Defendants and seek compensatory damages, disgorgement, restitution, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as

the Court deems just and proper.

FOURTH CAUSE OF ACTION

(Violation of Business & Profession Code § 17500)

244. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

245. Plaintiffs are informed and believe and thereon allege that Defendants, by the acts and misconduct alleged herein, violated Business & Professions Code Section 17500.

246. Plaintiffs hereby seek restitution, as well as and punitive damages against Defendant Lilly for their violations of section 17500.

247. California Business & Professions Code section 17500 provides that it is unlawful for any person, firm, corporation or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.

248. At all times herein mentioned, Defendant Lilly has committed the acts of disseminating untrue and misleading statements as defined by Business & Professions Code Section 17500 by engaging in the following acts and practices with intent to induce members of the public to purchase and use Zyprexa:

a. Representing to the State of California and the general public that Zyprexa was safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the State of California and the general public that Zyprexa has a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians and others that the use of Zyprexa was safe for human use, had fewer side effects and adverse reactions than other methods for treating mental illness, constituted a convenient, safe form for treating mental illness, even though the Defendant

Lilly knew these to be false, and even though the Defendant Lilly had no reasonable grounds to believe them to be true;

c. Purposely downplaying and understating the health hazards and risks associated with Zyprexa; and

d. Issuing promotional literature deceiving potential users of Zyprexa by relaying positive information and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of Zyprexa.

249. The foregoing practices constitute false and misleading advertising within the meaning of California Business & Professions Code Section 17500.

250. As a result of its false and misleading statements described above, Defendant Lilly has been and will be unjustly enriched. Specifically, Defendant Lilly has been unjustly enriched by receipt of billions of dollars from the sale and prescription of Zyprexa in California and other states, sold in large part as a result of the false or misleading statements described herein.

251. Pursuant to California Business & Professions Code Section 17535, Plaintiffs seek an order of this court compelling Defendant Lilly to provide restitution, and to disgorge the monies collected and profits realized by Defendant Lilly, as a result of their unfair business practices, and injunctive relief calling for Defendant Lilly to cease such unfair business practices in the future.

JURY DEMAND

443. Plaintiffs demand trial by jury on all claims.

WHEREFORE, Relator-Plaintiff, on behalf of herself, and the State of California and the State of California, requests the following relief:

(a) Judgment against Defendant Lilly in the amount of three (3) times the amount of damages the State of California has sustained because of Defendant Lilly's actions, plus a civil penalty of $10,000.00 for each action in violation California False

Claims Act, Cal. Gov. Code §§ 12650 et seq., and the appropriate fines and penalties for violating the protective California laws applicable to the fraudulent and false conduct and the cost of this action with interest;

(b) That Plaintiff-Relator be awarded the maximum amount allowed pursuant to the California False Claims Act, Cal. Gov. Code §12651(a), plus interest, and all relief to which she is entitled pursuant to said laws;

(c) That the Plaintiff-Relator be awarded all costs incurred, including reasonable attorneys' fees;

(d) In the event that the State of California proceed with this action, Plaintiff-Relator Vicente, be awarded an appropriate amount for disclosing evidence or information that the State of California did not possess when this action was brought to the government. The appropriate amount is not greater than twenty-five percent (25%) of the proceeds of the action or settlement of a claim. The amount awarded to Plaintiff-Relator also includes the results of government actions or settlement of claims resulting from the expansion of claims through the government's further investigation directly generated from or attributable to Plaintiff-Relator's information; and,

(e) Such other relief as this Court deems just and appropriate.

DATED: May 11, 2007.

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EXHIBIT A

Why is Lilly expanding its Long Term Care Business?

- To improve care & maximize Zyprexa & Prozac sales for residents who receive their medications via a LTC pharmacy
- To build a LTC business that is the industry model which will:
  - Maximize Lilly's rich pipeline of future products
  - Attract external products to Lilly which will enhance our rich pipeline

The Golden Opportunity in Long Term Care

- One of the fastest growing segments of the US population
  - Mental disorders are common
  - Use a lot of prescription drugs

  Many of Lilly's current & future products address the unmet medical needs of LTC patients (i.e. mental disorders, diabetes/complications, osteoporosis, urinary incontinence, etc.)
- According to market research, over 50% of all residents are prescribed some type of psychoactive medicine
- Building a LTC business that is the industry model may attract external product partnerships

Building the Lilly LTC Business
160
Representatives
March, 2000
59
Representatives
August, 1999
15
Representatives

Mike Murray

Q1 Expectations for LTC - W

- Selling to Existing Customers (Continue Current Momentum)
  - Seamless Transfer of Information Between Representatives
  - Impeccable Customer/Product & Disease Knowledge
  - Ability to Deliver Core Messages
  - Ability to Create Action
- Develop Deep Understanding of LTC Network in Each DGA
- Identify Key Influencers and Maximize Selling Opportunities in LTC Network